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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,724	01/15/2002	Vince Hilser	HO-P02070US1	5156

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EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/047,724	Applicant(s) HILSER ET AL.	
	Examiner Cheyne D. Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22, 34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 34 and 35 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/03/05</u> . | 6) <input type="checkbox"/> Other: _____ |

S.G.O.

DETAILED ACTION

1. Applicants' arguments filed February 14, 2005 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The new title and drawings have been accepted.
3. The IDS, filed March 03, 2005, has been considered.
4. The cancellation of claims 1-18, 23-33, and 36-38 has been acknowledged.
5. It is noted that the claim amendment in claim 19, line 4, has written description support on page 17, [0069], in the instant specification.
6. Claims 19-22, 34, and 35 are examined on the merits.

OBJECTIONS

7. Claim 19 is objected to because said claim does not end with a period. Appropriate correction is required.

CLAIM REJECTIONS - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 19-22, 34, and 35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory algorithm type subject matter.

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10. This rejection is maintained with respect to claims 19-22, 34, and 35, as recited in the previous office action mailed August 17, 2004.

RESPONSE TO ARGUMENTS

11. On page 5, Applicant argues the amendment has overcome the instant rejection because said amendment cause claim 19 to “more specifically reflect a practical application.” It is noted that the disclosure on pages 5-6, [0024], discusses the advantages of the claimed invention has been reasonably construed an assertion of “practical application” of said invention. However, Applicant’s argument via claim amendment is not persuasive because the claim amendment has been reasonably construed as an algorithmic process which does not result in the controlling of any physical steps resulted from the data manipulation. Therefore, the claimed invention, as a whole, does not accomplish a practical application. That is, it does not produce a “useful, concrete and tangible result.”

12. “For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the mathematical algorithm is statutory.” (MPEP § 2106 (IV)(B)(2) (b), part ii). The step of filtering noise is controlled by the results generated from the data manipulation. The difference between the claimed invention and the citation above is that the instant claims recite limitations directed to data manipulation without any limitation which could reasonably be construed as

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13. Specific to the computer-readable medium of claims 34 and 35, the MPEP § 2106 (IV)(B)(2) (a) describes via *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 149 F. 3d 1368, 1374, 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998), the "[T]ransformation of data, representing discrete dollar amounts, by a machine through a series of mathematical calculations into a final share price, constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces a useful, concrete and tangible result' -- a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades." The discussion directed to "a final share price momentarily fixed for recording and reporting purposes and even accepted and relied upon by regulatory authorities and in subsequent trades" has been reasonably construed as the controlling of a physical step resulted from said data manipulation. The difference between the claimed invention and the citation above is that the instant claims recite limitations directed to data manipulation without any limitation which could reasonably be construed as controlling any physical steps resulted from said data manipulation.

BASIS FOR REJECTION

14. Claims 19-22, 34, and 35 are rejected because said claims are directed to a method and computer readable medium comprising algorithmic steps for analyzing protein data without any physical alteration step, which is considered to be non-statutory subject matter. "For example, a computer process that simply calculates a mathematical algorithm that models noise is nonstatutory. However, a claimed process for digitally filtering noise employing the

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mathematical algorithm is statutory.” (MPEP § 2106 (IV)(B)(2) (b), part ii). Similar to the nonstatutory example above, the instant invention comprises algorithmic steps for analyzing protein data without any physical alteration resulted from said analysis or modeling steps.

15. It is acknowledged that the instant invention comprises a computer readable medium for performing the steps of analyzing protein data, however, said steps do not cause any physical alteration outside of said computer readable medium as a result of said analysis. Therefore, “such activity is not determinative of whether the process is statutory because such transformation alone does not distinguish a statutory computer process from a nonstatutory computer process” (MPEP § 2106 (IV)(B)(2) (b), part ii).

CLAIM REJECTIONS - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 19-22, 34, and 35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Hilser et al. (1996).

18. This rejection is maintained with respect to claims 19-22, 34, and 35, as recited in the previous office action mailed August 17, 2004.

RESPONSE TO ARGUMENTS

19. On pages 5-6, Applicant argues that “Hilser et al. do not teach or suggest how to identify a protein fold.” Applicant’s argument is not persuasive as discussed below.

20. It is noted that the instant specification, page 12, [0049], discloses the “term ‘protein fold’ as used herein refers to an organization of a protein to form a structure which constrains individual amino acids to a specific location relative to the other amino acids in the sequence. One of skill in the art realizes that this type of organization of a protein comprises secondary, tertiary and quarternary structures.” Hilser et al. discloses “we presented a structure-based thermodynamic approach aimed at identifying the structural determinants of intermediate protein conformations... Here, we have extended and refined that system of computer simulations to the point in which folding probabilities for individual amino acid residues can be estimated” (column 757, column 1, last paragraph). Therefore, Hilser et al. as cited anticipates the limitations of claims 19-22, 34, and 35 as described in the instant specification.

21. Specific to the argument “Hilser et al. (1996) teach a statistical description of conformation states... the reference does not teach or suggest how to identify protein folds, it is noted that claims 19-22, 34, and 35 recite “A method of identifying a protein fold”, but not “protein folds” as argued by Applicant. Further, it is noted that the method of Hilser et al. requires the calculation of folding probabilities for individual amino acid residues in a protein. However, such disclosure does not cause Hilser et al. to not anticipate the instant

invention as claimed. As discussed above and cited below, Hilser et al. anticipates the claimed invention as recited by claims 19-22, 34, and 35.

22. On page 6, Applicant argues that the Figure 1 and Table 1 of Hilser et al. is not “a scoring matrix.” It is noted that the instant specification does not specifically define the limitation of “scoring matrices.” The instant specification provides an example of “scoring matrices” such as the one discloses on page 27, Table 3. However, exemplary disclosure does not limit or specifically define the limitation recited in claim 22. Therefore, the citation of Figure 1 which describes residue 3 has the highest kr, while residue has the lowest (page 759, column 2), and Table 2 has been reasonably construed as the type of “scoring matrices” required by claim 22.

23. On page 6, Applicant argues that “Hilser et al. (1996) do not teach or suggest all the elements of the computer-based algorithm of the claimed invention.” Further, Applicant argues that “this computer-based algorithm is aimed at estimating the entire set of statistical descriptors of the equilibrium folding pathway.” Applicant’s argument is not persuasive as discussed below. It is noted that the argued limitation of “this computer-based algorithm is aimed at estimating the entire set of statistical descriptors of the equilibrium folding pathway” is not present in any of the claims. Therefore, the citation of the argued limitation, not present in the claims, is not required for anticipation basis. Further, the method of Hilser et al. is computer implemented (page 760, column 2, Computer modeling strategy §) using the MOLSCRIPT program (page 769, Figure 9). Further, Hilser et al. has extended and

refined that system of computer simulations to the point in which folding probabilities for individual amino acid residues can be estimated” (column 757, column 1, last paragraph).

BASIS FOR REJECTION

24. Hilser et al. discloses a method of calculating the equilibrium-folding pathway of proteins as directed to different thermodynamic environments corresponding to known proteins (Abstract etc.), as in instant claim 19.

25. The method of Hilser et al. involves the calculation of the relative heat capacity, enthalpy, and entropy of each state at the desired temperature (page 762, column 1, lines 13-28), as in instant claims 20 and 22.

26. The method of Hilser et al. comprises the generation of partly folded states by COREX algorithm (page 760, column 2) and constructing scoring matrices derived of thermodynamic information for determining the distribution of amino acids (Figure 1 and Table 1), as in instant claim 21.

27. The method of Hilser et al. is computer implemented (page 760, column 2, Computer modeling strategy §) using the MOLSCRIPT program (page 769, Figure 9), as in instant claims 34 and 35.

CONCLUSION

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

29. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

30. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

31. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic

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32. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

34. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly / *cd*
5/5/05

Ardin H. Marschel 5/14/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER